

substantially enforcing the requirements of this part, HCFA follows the following procedures:

(1) *Verification of exhaustion.* HCFA makes a threshold determination of whether the individuals affected by the alleged failure to enforce have made a reasonable effort to exhaust any State remedies. This may involve informal contact with State officials about the questions raised.

(2) *Notice to the State.* If HCFA is satisfied that there is a reasonable question about whether there has been a failure to substantially enforce the requirements of this part, HCFA sends, in writing, the notice described in paragraph (c)(3) of this section, to the following State officials:

(i) The Governor or chief executive officer of the State.

(ii) The insurance commissioner or chief insurance regulatory official.

(iii) If the alleged failure involves HMOs, the official responsible for regulating HMOs, if different than the official listed in paragraph (c)(2)(ii) of this section.

(3) *Form and content of notice.* HCFA's written notice to the State sets forth the following information:

(i) Describes the facts of the specific violations.

(ii) Explains that the consequence of a failure to substantially enforce the requirements of this part is that HCFA enforces the requirements in accordance with paragraph (d) of this section.

(iii) Advises the State that it has 45 days to respond to the notice, unless the time is extended as described in paragraph (c)(4) of this section, and that the response should include any information that the State wishes HCFA to consider in making the preliminary determination described in paragraph (c)(5) of this section.

(4) *Extension.* HCFA may, for good cause, grant the State an extension of the time period described in paragraph (c)(3)(iii) of this section. Examples of good cause include an agreement between HCFA and the State that there should be a public hearing on the State's enforcement, or evidence that the State is undertaking expedited enforcement activities.

(5) *Preliminary determination.* If, at the end of the 45-day period for a State

to respond to HCFA's notice (and any extension), the State has not established to HCFA's satisfaction that it is substantially enforcing the requirements of this part, HCFA takes the following actions:

(i) Consults with the officials described in paragraph (c)(1) of this section.

(ii) Notifies the State of HCFA's preliminary determination that the State has failed to enforce the requirements, and that the failure is continuing.

(iii) Permits the State a reasonable opportunity to show evidence of substantial enforcement.

(6) *Final determination.* If, after providing notice and the opportunity to enforce the requirements of this part, HCFA finds that the failure to enforce has not been corrected, HCFA sends the State a written notice of that final determination. The notice sets forth the following:

(i) The effective date of HCFA enforcement.

(ii) The mechanism for establishing in the future that it has corrected the failure, and has begun enforcement. This mechanism includes transition procedures for ending HCFA's enforcement period.

[62 FR 17002, Apr. 8, 1997]

EFFECTIVE DATE NOTE: At 62 FR 17002, Apr. 8, 1997, § 148.200 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 148.202 Civil money penalties.

(a) *General rule.* If any health insurance issuer that is subject to HCFA's enforcement authority under § 148.200 fails to comply with any applicable requirement of this part, it may be subject to a civil money penalty.

(b) *Complaint.* Any person who is entitled to any right under this part, and who believes that the right is being denied as a result of an issuer's failure to comply with the requirements of this part may file a complaint with HCFA.

(c) *Notice to issuer.* HCFA sends a written notice to the issuer that a complaint or other information has been received alleging a violation of this part. The notice sets forth the following:

(1) A description of the substance of any complaint or other allegation.

(2) A time frame of 30 days for the issuer to respond with additional information, which can include the following:

(i) Information refuting that there has been a violation.

(ii) Evidence that the issuer did not know, and exercising reasonable diligence could not have known, of the violation.

(iii) Evidence of a previous record of compliance.

(d) *Notice of assessment.* If, based on the information provided in the complaint, as well as any information submitted by the issuer or any other parties, HCFA proposes to assess a civil money penalty, HCFA sends written notice of the assessment to the issuer by certified mail, return receipt requested. The notice contains the following information:

(1) The name or names of the individuals with respect to whom a violation occurred, with relevant identification numbers.

(2) The facts that support the finding of a violation, and the initial date of the violation.

(3) The amount of the proposed penalty as of the date of the notice.

(4) The basis for calculating the penalty, including consideration of prior compliance.

(5) Instructions for responding to the notice, including the following information:

(i) A specific statement of the issuer's right to a hearing.

(ii) A statement that failure to request a hearing within 30 days permits the imposition of the proposed penalty, without right of appeal.

(e) *Amount of penalty—(1) Maximum daily penalty.* The penalty cannot exceed \$100 for each day, for each individual with respect to whom a failure occurs.

(2) *Standard for calculating daily penalty.* In calculating the amount of the penalty, HCFA takes into account the issuer's previous record of compliance and the seriousness of the violation.

(3) *Limitations on penalties.* No civil money penalty is imposed for the following periods:

(i) A period during which a failure existed, but the issuer did not know, and exercising reasonable diligence would not have known, that the failure existed.

(ii) A period occurring immediately after the period during which a failure existed, but the issuer did not know, and exercising reasonable diligence would not have known, that the failure existed if the failure—

(A) Was due to reasonable cause and was not due to willful neglect; and

(B) Was corrected within 30 days of the first day that the issuer knew, or exercising reasonable diligence would have known, that the failure existed.

(iii) The burden is on the issuer to establish to the satisfaction of HCFA that it did not know, and exercising reasonable diligence could not have known that the failure existed.

(f) *Hearings—(1) Right to a hearing.* Any issuer against which a penalty is assessed may request a hearing by HCFA. The request must be in writing, and must be postmarked within 30 days after the date HCFA issues the notice of assessment.

(2) *Failure to request a hearing.* If no hearing is requested in accordance with this paragraph (f), the notice of assessment constitutes a final order that is not subject to appeal.

(3) *Parties to the hearing.* Parties to the hearing include the issuer and the party who filed the complaint. HCFA sends an informational notice to the State.

(4) *Initial agency decision.* The initial agency decision is made by an administrative law judge. The decision is made on the record under section 554 of Title 5, United States Code. The decision becomes a final and appealable order after 30 days, unless it is modified in accordance with paragraph (g) of this section.

(5) *Review by HCFA.* HCFA may modify or vacate the initial agency decision. Notice of intent to modify or vacate the decision is issued to the parties within 30 days after the date of the decision by the administrative law judge.

(g) *Judicial review—(1) Filing of action for review.* Any issuer against whom a final order imposing a civil money penalty is entered may obtain review in

the United States District Court for any district in which the entity is located or the United States District Court for the District of Columbia by—

(i) Filing a notice of appeal in that court within 30 days from the date of a final order; and

(ii) Simultaneously sending a copy of the notice of appeal by registered mail to HCFA.

(2) *Certification of administrative record.* HCFA promptly certifies and files with the court the record upon which the penalty was imposed.

(3) *Standard of review.* The findings of HCFA may not be set aside unless they are found to be unsupported by substantial evidence, as provided by section 706(2)(E) of Title 5, United States Code.

(4) *Appeal.* Any final decision, order, or judgment of the district court concerning HCFA's review is subject to appeal as provided in Chapter 83 of Title 28, United States Code.

(h) *Failure to pay assessment, maintenance of action—*(1) *Failure to pay assessment.* If an issuer fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of HCFA, HCFA refers the matter to the Attorney General, who brings an action against the issuer in the appropriate United States district court to recover the amount assessed.

(2) *Final order not subject to review.* In an action brought under paragraph (h)(1) of this section, the validity and appropriateness of the final order described in paragraph (g)(1)(i) or paragraph (g)(3) of this section is not subject to review.

(i) *Use of penalty funds.* (1) Any funds collected under this section are paid to HCFA.

(2) The funds are available without appropriation and until expended.

(3) The funds may only be used for the purpose of enforcing the provisions for which the penalty was imposed.

[62 FR 17002, Apr. 8, 1997; 62 FR 31696, June 10, 1997]

EFFECTIVE DATE NOTE: At 62 FR 17002, Apr. 8, 1997, § 148.202 was added. This section contains information collection and record-keeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 148.210 Preemption.

(a) *Scope.* (1) This section describes the effect of sections 2741 through 2763 and 2791 of the PHS Act on a State's authority to regulate health insurance issuers in the individual market. This section makes clear that States remain subject to section 514 of ERISA, which generally preempts State law that relates to ERISA-covered plans.

(2) Sections 2741 through 2763 and 2791 of the PHS Act cannot be construed to affect or modify the provisions of section 514 of ERISA.

(b) *Regulation of insurance issuers.* The individual market rules of this part do not prevent a State law from establishing, implementing, or continuing in effect standards or requirements unless the standards or requirements prevent the application of a requirement of this part.

§ 148.220 Excepted benefits.

The requirements of this part do not apply to individual health insurance coverage in relation to its provision of the benefits described in paragraphs (a) and (b) of this section (or any combination of the benefits).

(a) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances:

(1) Coverage only for accident (including accidental death and dismemberment).

(2) Disability income insurance.

(3) Liability insurance, including general liability insurance and automobile liability insurance.

(4) Coverage issued as a supplement to liability insurance.

(5) Workers' compensation or similar insurance.

(6) Automobile medical payment insurance.

(7) Credit-only insurance (for example, mortgage insurance).

(8) Coverage for on-site medical clinics.

(b) *Other excepted benefits.* The requirements of this part do not apply to individual health insurance coverage described in paragraphs (b)(1) through (b)(6) of this section if the benefits are provided under a separate policy, certificate, or contract of insurance. These benefits include the following: